UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Milanesi, et al. v. C.R. Bard, Inc., et al.
Case No. 2:18-cv-01320

EVIDENTIARY MOTIONS OPINION & ORDER No. 24

Before the Court are Plaintiffs' Motions to Exclude the Opinions and Testimony of Defense Experts Donna-Bea Tillman, Ph.D. (ECF No. 73), Kimberly Trautman, M.S. (ECF No. 75), Greg Richey (ECF No 76), Thomas Michel Galassi, MPH, CIH (ECF No. 78), Robert D. Tucker, Ph.D., M.D. (ECF No. 80), Marion J. Fedoruk, M.D. (ECF No. 83), and David Kessler, M.D. (ECF No. 69). These expert opinions primarily address the Food and Drug Administration ("FDA") and Material Safety Data Sheets ("MSDSs"). For the reasons that follow, Plaintiffs' motions addressing Dr. Tillman (ECF No. 73), Trautman (ECF No. 75), and Dr. Tucker (ECF No. 80) are each **GRANTED IN PART AND DENIED IN PART**; Plaintiffs' motions addressing Richey (ECF No 76), Galassi (ECF No. 78), and Dr. Fedoruk (ECF No. 83) are each **GRANTED**; and Plaintiffs' motion addressing Dr. Kessler (ECF No. 69) is **DENIED AS MOOT**.

I. Background[1]

Plaintiffs', Antonio Milanesi and Alicia Morz de Milanesi, case is the second bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants,

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. (ECF No. 167.)

C.R. Bard, Inc. and Davol, Inc. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (Case No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)[2] This includes Defendants' Ventralex Hernia Patch, the device implanted in Mr. Milanesi.

The Ventralex is a prescription medical device used for umbilical and small ventral hernia repairs. (ECF No. 167 at PageID #13610.) The small and medium sizes were cleared through the 510(k) premarket notification process by the Food and Drug Administration ("FDA") in 2002; the Composix Kugel was listed as a predicate device. (*Id.* at PageID #13611.) The large size was cleared via "a no 510(k) rationale based upon the 510(k) for the Composix Kugel product." (*Id.*) The Ventralex has two sides—one of polypropylene mesh and one of permanent expanded polytetrafluoroethylene ("ePTFE"). (*Id.* at PageID #13610.) The polypropylene mesh side faces the abdominal wall, encouraging tissue to grow into the mesh and thus supporting the hernia repair. The ePTFE side faces the intestines and is designed to minimize tissue attachment, such as adhesions, to the intestines and other viscera. The Ventralex also has a monofilament memory coil ring, which was made of polyethylene terephthalate ("PET") when it was implanted in Mr. Antonio. The ring is designed to help the patch "pop open" and then "lay flat" against the abdominal wall after the Ventralex is folded and inserted through the incision site during surgical repair of the hernia. (*Id.*)

[2] All docket citations are to the docket in the instant case, Case No. 18-cv-1320, unless otherwise noted.

Plaintiffs bring this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralex device. Ten years after the implantation of the Ventralex, Mr. Milanesi underwent surgery to repair what appeared to be a recurrent hernia but was revealed to be a bowel erosion with a fistula and adhesions, which required a bowel resection. (*Id.* at PageID #13611–13.) Shortly thereafter, Mr. Milanesi suffered a high-grade post-operative small bowel obstruction that required emergency surgery. (*Id.* at PageID #13613.)

The crux of Plaintiffs' claims is that Defendants knew of the risks presented by the Ventralex device but marketed and sold the device despite these risks and without appropriate warnings. Plaintiffs point to three specific issues with the Ventralex: (1) polypropylene resin oxidatively degrades *in vivo*, (2) the ePTFE layer contracts more quickly than the polypropylene, which in combination with the too-weak memory coil ring causes the device to fold or buckle or "potato chip," leading to the exposure of the bare polypropylene to the bowel, and (3) the ePTFE layer is prone to infection. (*Id.* at PageID #13613–14.) After summary judgment, the following claims remain for trial: defective design (strict liability), failure to warn (strict liability), negligence, gross negligence, negligent misrepresentation, fraud and fraudulent misrepresentation, fraudulent concealment, loss of consortium, and punitive damages. (*Id.* at PageID #13616–37.)

The parties have filed their dispositive and *Daubert* motions, and the motions are now ripe for adjudication, including the present motion.

II. Legal Standard

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of

trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because courts are "almost always better situated during the actual trial to assess the value and utility of evidence." *Jackson v. Cnty. of San Bernardino*, 194 F. Supp. 3d 1004, 1008 (C.D. Cal. July 5, 2016) (quoting *Wilkins v. Kmart Corp.*, 487 F. Supp. 2d 1216, 1218 (D. Kan. 2007)); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975) ("A better practice is to deal with questions of admissibility of evidence as they arise."). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (quoting *Ind. Ins. Co*., 326 F. Supp. 2d at 846). The denial, in whole or in part, of a motion in limine does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

The burden is on the party offering the expert opinions and testimony to demonstrate "by a preponderance of proof" that the expert evidence is admissible. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Any doubts regarding the admissibility of an expert's testimony should be resolved in favor of admissibility. *See Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) ("The Court [in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993),] explained that Rule 702 displays a 'liberal thrust' with the 'general approach of relaxing the traditional barriers to "opinion" testimony.'" (quoting *Daubert*, 509 U.S. at 588)); Fed. R. Evid.

702 advisory committee's note to 2000 amendment ("A review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.").

III. Analysis

The district court's role in assessing expert testimony is a "gatekeeping" one, "screening expert testimony" so that only admissible expert testimony is submitted to the jury; its role is not to weigh the expert testimony or determine its truth. *United States v. Gissantaner*, 990 F.3d 457, 463 (6th Cir. 2021) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). Expert testimony, testimony given by "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education," is admissible if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. In this circuit, "[t]he Rule 702 analysis proceeds in three stages." *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016). "First, the witness must be qualified by 'knowledge, skill, experience, training, or education.' Second, the testimony must be relevant, meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' Third, the testimony must be reliable." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (quoting Fed. R. Evid. 702.).

First, an expert witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "[T]he issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation

for a witness to answer a specific question." *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). "[T]he only thing a court should be concerned with in determining the qualifications of an expert is whether the expert's knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert's testimony must be for the trier of fact." *Mannino v. Int'l Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981). A party's expert need only meet the "'minimal qualifications' requirement—not one who could teach a graduate seminar on the subject." *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014) (quoting *Mannino*, 650 F.2d at 851); *see also Dilts v. United Grp. Servs., LLC*, 500 F. App'x 440, 446 (6th Cir. 2012) ("An expert's lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact.").

Second, expert testimony must be relevant. Expert testimony is relevant if it will "help the trier of fact to understand the evidence or to determine a fact in issue." *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 208 (6th Cir. 2015) (quoting *United States v. Freeman*, 730 F.3d 590, 599–600 (6th Cir. 2013)); Fed. R. Evid. 702(a). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (quoting 3 Jack B. Weinstein & Margaret A. Berger, Weinstein's Evidence ¶ 702[02], p. 702–18 (1988)). "This requirement has been interpreted to mean that scientific testimony must 'fit' the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592). This is a case-specific inquiry. *See Madej*, 951 F.3d at 370 ("Whether an opinion 'relates to an issue in the case' or helps a jury answer a 'specific question' depends on the claims before the court.").

Third, expert testimony must be reliable. Rule 702 provides the following general standards to assess reliability: whether "the testimony is based on sufficient facts or data," whether "the testimony is the product of reliable principles and methods," and whether "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)–(d). To evaluate reliability of principles and methods, courts consider "'testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community,'" though these "factors 'are not dispositive in every case' and should be applied only 'where they are reasonable measures of the reliability of expert testimony.'" *In re Scrap Metal*, 527 F.3d at 529 (citations omitted); *see Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (describing these factors as "flexible" (quoting *Daubert*, 509 U.S. at 594)). The objective of the reliability requirement is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

Plaintiffs move for the exclusion of expert opinions and testimony from the following defense experts: Donna-Bea Tillman, Ph.D.; Kimberly Trautman, M.S.; Greg Richey; Thomas Michel Galassi, MPH, CIH; Robert D. Tucker, Ph.D., M.D.; and Marion J. Fedoruk, M.D.

A. Donna-Bea Tillman, Ph.D.

Plaintiffs argue that Dr. Tillman's opinions on the meaning of the MSDS, opinions regarding the FDA's quality system regulations, and any testimony related to the FDA websites that discuss mesh should be excluded. (ECF No. 73 at PageID #3723, 3732.) The Court's earlier evidentiary opinion on Dr. Tillman addresses these arguments fully.

Dr. Tillman's MSDS and FDA website opinions are inadmissible, but her opinions regarding the FDA's quality systems regulations are admissible. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, No. 2:18-cv-1509, 2021 WL 2643109, at *6–7 (S.D. Ohio June 28, 2021) (Evidentiary Motions Order ("EMO") No. 9).

Three new arguments warrant discussion. First, Defendants point to this Court's motion in limine opinion holding that the MSDS is admissible only to prove notice. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6603657, at *2–5 (S.D. Ohio Oct. 20, 2020) (Motions in Limine Order ("MIL") No. 4). Although the briefing on Dr. Tillman in *Johns v. C.R. Bard, Inc.*, the first bellwether case in the MDL, was completed before the Court issued MIL No.4, the Court accounted for this motion in limine opinion in its evidentiary opinion addressing Dr. Tillman. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2643109, at *6 (EMO No. 9). Second, Defendants point to the Court's previous motion in limine opinion on the FDA website. (ECF No. 100 at PageID #8566.) In *Johns*, the Court denied the plaintiff's motion in limine regarding the FDA hernia mesh website, so long as the FDA website was from the relevant time frame. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6603657, at *11 (MIL No. 4). However, this holding has no impact on the Court's earlier evidentiary holding on Dr. Tillman's FDA website opinion, specifically that Dr. Tillman lacks knowledge about the FDA's vetting process for this website. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2643109, at *7 (EMO No. 9). Third, Plaintiffs argue that Dr. Tillman's testimony is duplicative in light of Dr. Trautman's testimony. (ECF No. 125 at PageID #11006.) The Court declines to rule on this issue outside of the context of trial.

For these reasons, Plaintiffs' motion (ECF No. 73) is **GRANTED IN PART AND DENIED IN PART**.

B. Kimberly Trautman, M.S.

Plaintiffs assert that Trautman is unqualified to opine on whether Defendants are in acceptable standing with the FDA and whether the FDA considers Defendants' products safe, and that her opinions are unreliable. (ECF No. 75 at PageID #4136–41.) Plaintiffs' brief in support of their motion and Defendants' response brief raise the same arguments. (*Compare* ECF Nos 75 & 96 *with* Case No. 18-cv-1509, ECF Nos. 72& 111.) Accordingly, the Court's previous *Daubert* opinion on Trautman applies. Trautman is qualified to offer her opinions, but she cannot opine on the FDA's beliefs, removing the need to address Plaintiffs' arguments that her FDA-belief opinions are unreliable. *In re Davol, Inc./C.R. Bard Inc.*, 2021 WL 2643109, at *7–8 (EMO No. 9).

Plaintiffs also argue that Trautman's other opinions are unreliable because she did not review documents, "skimmed" certain documents, or did not adequately note or consider certain documents, or placed too much reliance on certain documents. (ECF No. 75 at PageID #4140–41; ECF No. 129 at PageID #11189–92.) Plaintiffs do not show that Trautman's opinion are unreliable; they only show that they disagree with Trautman's opinions. These issues go to the weight of the testimony. It is sufficient that Plaintiff may cross-examine Trautman.

For these reasons, Plaintiffs' motion (ECF No. 75) is **GRANTED IN PART AND DENIED IN PART**.

C. Greg Richey

Plaintiffs move to exclude the opinions and testimony of Greg Richey. (ECF No. 76.) Defendants contend that Richey should be permitted to testify as to the meaning of the MSDS and what Defendants' response to the MSDSs, either the Marlex or Pro-fax MSDS, should have been in the event that Plaintiffs are permitted to present evidence of the meaning of the MSDS. (ECF No. 93 at PageID #7349). These are the same arguments raised in relation to the earlier *Daubert* motion in *Johns* addressing Richey. (*Compare* ECF Nos. 76, 93, & 127 *with* Case No. 18-cv-1509, ECF Nos. 97, 125, & 139.) Therefore, the Court adheres to its previous evidentiary opinion granting Plaintiffs' motion to exclude Richey's testimony. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2643109, at *9 (EMO No. 9). No expert may opine on the meaning and context of an MSDS, and an MSDS is only admissible to Defendants' notice of the risks posed by polypropylene. *Id.*

Thus, Plaintiffs' motion (ECF No. 76) is **GRANTED**.

D. Thomas Michel Galassi, MPH, CIH

Plaintiffs argue that Galassi is unqualified to offer his MSDS opinions and that his MSDS opinions are unreliable. (ECF No. 78 at PageID #4646–54.) They also contend that Galassi's related opinions are unreliable. (*Id.* at PageID #4654–56.) Defendants argue that in the event evidence of the MSDS is admitted, Defendants should be permitted to offer Galassi's testimony. (ECF No. 91 at PageID #7081–82.) These are the same arguments as those in the first bellwether case, *Johns*. (*Compare* ECF Nos 78, 91, & 128 *with* Case No. 18-cv-1509, ECF Nos. 138, 153 & 156.) For this reason, the Court's previous evidentiary opinion on Galassi applies: "As with other regulatory experts, Galassi's MSDS opinions are inadmissible because they do not speak to what Defendants

knew about the risks of polypropylene from the Marlex MSDS. Accordingly, Galassi's opinions related to MSDSs are irrelevant and inadmissible." *In re Davol, Inc./C.R. Bard Inc.*, 2021 WL 2643109, at *9 (EMO No. 9).

Plaintiffs' motion (ECF No. 78) is therefore **GRANTED**.

E. Robert D. Tucker, Ph.D., M.D.

Plaintiffs move to exclude Dr. Tucker's opinions and testimony, specifically his causation, FDA, pore-size, and MSDS opinions. (ECF No. 80 at PageID #5036–43.) These are largely the same issues raised in corresponding *Daubert* motion in *Johns*. (*Compare* ECF Nos. 80, 99, & 132 *with* Case No. 18-cv-1509, ECF Nos. 42, 87, & 104.) The Court's evidentiary opinion on the matter resolves the causation, pore-size, and MSDS issues; Dr. Tucker's causation and pore-size opinions are admissible but his MSDS opinion is not. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, 2:18-cv-1509, 2021 WL 2643114, at *3–6 (S.D. Ohio June 28, 2021) (EMO No. 11).

In the Court's earlier opinion, it concluded that Dr. Tucker's opinions about FDA approval and clearance of the Ventralex device and the Prolene suture were inadmissible because they were irrelevant. *Id.* at *4. The reasoning regarding the Prolene suture still holds here: "Although it appears that the Prolene suture is also made of polypropylene, there is no indication that the Prolene suture is a component part of the [Ventralex] or otherwise directly connected to the [Ventralex]." *Id.* For instance, Defendants do not contend that Prolene polypropylene is the same as in this case. But the Court's view that the Ventralex opinion is irrelevant to the Ventralight-ST case must be revisited because this case is about the Ventralex device. *See id.*

Plaintiffs challenge Dr. Tucker's statement that "[t]he Ventralex was cleared by the FDA in 2002 for the product with a PET ring. In 2013 a new 510(k) was cleared for changing he PET ring to PDO (polydioxanone)." (ECF No. 80 at PageID #5037.) There is nothing objectionable to this statement. The use of the term "cleared" is accurate and the Court's instruction on the 510(k) process will avoid any jury confusion. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6603657, at *7–9 (MIL No. 4). Moreover, "[e]vidence of the 510(k) process for the [Ventralex] is admissible in this case because it is part of the story of the [Ventralex]." *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2643114, at *5 (EMO No. 11).

For these reasons, Plaintiffs' motion is **GRANTED IN PART AND DENIED IN PART**.

F. Marion J. Fedoruk, M.D.

Plaintiffs move to exclude the opinions and testimony of Dr. Fedoruk (ECF No. 83), whom Defendants contend should be permitted to testify as to the meaning of the MSDS, including why the polypropylene manufacturer included the Medical Application Caution statement, and how the FDA views the MSDS in relation to manufacturer submissions to the FDA (ECF No. 90 at PageID #7058). The parties raise largely the same arguments as in the earlier *Daubert* motion in *Johns* addressing Dr. Fedoruk. (*Compare* ECF Nos. 83, 90, & 135 *with* case No. 18-cv-1509, ECF Nos. 43, 83, & 105.) There is thus no justification to depart from the Court's previous opinion granting Plaintiffs' motion to exclude Dr. Fedoruk's testimony. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2643109, at *8 (EMO No. 9). His opinions are irrelevant because the MSDSs are only admissible to prove Defendants' knowledge of the risks presented by

polypropylene and because his opinions regarding the FDA's beliefs and the motivations behind the inclusion of the Medical Application Caution statement are improper topics of expert testimony. *Id.*

Thus, Plaintiffs' motion (ECF No. 83) is **GRANTED**.

G. David Kessler, M.D.

The Plaintiffs' Steering Committee in *Johns* represented to the Court that David Kessler, M.D. was no longer an expert in this MDL, leading the Court to deny as moot Defendants' *Daubert* motion addressing Kessler. (Case No. 18-cv-1509, ECF No. 448 at PageID #22726.) Accordingly, Defendants' Motion to Exclude or Limit the Opinions of Plaintiffs' Expert David Kessler, M.D. (ECF No. 69) is also **DENIED AS MOOT**.

IV. Conclusion

Accordingly, Plaintiffs' motions addressing Dr. Tillman (ECF No. 73) is **GRANTED IN PART AND DENIED IN PART**, Trautman (ECF No. 75) is **GRANTED IN PART AND DENIED IN PART**, Richey (ECF No 76) is **GRANTED**, Galassi (ECF No. 78) is **GRANTED**, Dr. Tucker (ECF No. 80) is **GRANTED IN PART AND DENIED IN PART**, Dr. Fedoruk (ECF No. 83) is **GRANTED**; and Dr. Kessler (ECF No. 69) is **DENIED AS MOOT**.

IT IS SO ORDERED.

11/2/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE